K955011

# 510(k) SUMMARY FOR CANDELA LASER CORPORATION'S CANDELA HCS 2000 URETHRAL WARMER CATHETER SYSTEM

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## Name of the Device

The Candela HCS 2000 Urethral Warmer Catheter System

## Common or Usual Name

Suprapubic Urethral Catheter and Heating System

## Classification Name

Suprapubic urethral catheter and warming systems have not been specifically classified by FDA. However, FDA has classified cryosurgical devices and accessories and suprapubic urological catheters and accessories as Class II devices under 21 C.F.R. §§ 878.4350 and 876.5090, respectively. Suprapubic urethral warmer catheter and heating systems, such as the Candela HCS 2000 Urethral Warmer Catheter System ("the Candela Urethral Warmer"), also are Class II devices as accessories to the cryosurgical devices.

**Predicate Device**

Cryomedical Sciences, Inc.'s CMS Urethral Warmer (K952595)

**Intended Use**

The Candela HCS 2000 Urethral Warmer Catheter System is designed to transfer heat into the urethral membrane during cryosurgical ablation of prostatic tissue using the Cryotech LCS 3000 Cryosurgical System.

**Technical Characteristics**

The principal components of the Candela Urethral Warmer are: (1) a saline bottle filled with a saline solution; (2) infrared lamps; (3) a temperature controller; (4) a roller pump; (5) delivery tubing and a balloon catheter with a radiopaque marker at its center; (6) pump tubing (7) return tubing; (8) a urethral/bladder sound (K950633); and (9) a console. The console houses the saline reservoir, the infrared lamps, and the roller pump and digital temperature readouts and buttons for operating the device appear on the front of the console.

**Principles of Operation**

The principles of operation of the Candela Urethral Warmer are simple. The Candela Urethral Warmer is inserted suprapubicly. A sound is inserted through the urethra into the bladder where a conventional excision is made. The tubing is then attached to the sound and drawn through the bladder into the urethra and out of the penis. The marker at the center of the balloon is positioned using ultrasound and by pulling on the silicone tip of the tubing until the

marker is in the desired position. The delivery tubing is then connected to the saline bottle. The pump tubing, which is connected between two segments of the delivery tubing, is inserted into the roller pump. When the pump is started, heated saline circulates through the tubing and is returned to the saline bottle.

The operator turns the device on by pushing the power button on the console. He or she then sets the pump speed and selects the "forward" direction for the pump. The infrared lamps heat the saline in the bottle to the preset saline temperature. The infrared lamps cycle on and off to maintain the saline at approximately the preset temperature. The temperature of the saline in the bottle and within the tubing is displayed on two digital readouts. The roller pump continuously circulates the warm sterile saline through the urethra via the catheter tubing. An alarm sounds if the temperature is outside the acceptable range and the temperature controller will turn the infrared lamps on or off. An alarm will also sound if the volume of saline is low. The operator turns the device off by pushing the power switch and switching the pump speed to "zero."

**Summary Basis for the Finding of Substantial Equivalence**

The Candela Urethral Warmer has the same intended use as Cryomedical Sciences, Inc.'s CMS Urethral Warmer ("the CMS Urethral Warmer"). These devices also have very similar general principles of operation. In addition, suprapubic insertion of a urethral catheter is a well-recognized procedure that does not raise new questions of safety or effectiveness. The Candela Urethral Warmer

and the CMS Urethral Warmer also have the following components: (1) a balloon catheter; (2) a roller pump; (3) a saline container filled with saline; (4) delivery tubing; (5) return tubing; and (6) at least one digital temperature readout.

There are six principal technological differences between the Candela Urethral Warmer and the CMS Urethral Warmer.

First, the Candela Urethral Warmer has two digital temperature readouts while the CMS Urethral Warmer has one. The Candela Urethral Warmer also has an audible temperature alarm. Testing was conducted with open ended tubing, *i.e.*, with no balloon catheter attached, to determine at what temperatures the Candela Urethral Warmer's alarm sounded. The temperature controller was disabled from the infrared lamps, and the lamps were controlled manually. The lamps were turned on and the temperature was allowed to rise until the alarm sounded. The temperature was then recorded and the lamps turned off. The temperature was then allowed to fall until the alarm sounded. The temperature was recorded and the lamps turned on again. The saline temperature was cycled in this way until the alarm sounded 20 times for over temperatures and 20 times for under temperatures. The test results demonstrated that the alarm sounds when the temperature of the saline is outside the acceptable range. Thus, the differences in the Candela Urethral Warmer's temperature indicators do not raise any new questions of safety or effectiveness.

Second, the Candela Urethral Warmer and the CMS Urethral Warmer have different heat sources. The Candela Urethral Warmer uses infrared lamps. The CMS Urethral Warmer uses a hot plate. An experiment was conducted to determine whether the circulation of heated saline through the Candela Urethral Warmer warmed the tissue surrounding the balloon catheter at a low saline flow rate when cryoprobes were used without sheaths. In that experiment, a 3mm prostate cryoprobe and a 3mm trocar cryoprobe without sheaths were place in a dog kidney and the Candela Urethral Warmer was used to circulate heated saline through the kidney. Five thermocouples were used and the temperatures were recorded at one minute intervals for the first 12 minutes of the cryosurgical procedure. The cryosurgical device was used in the freeze mode for 18.5 minutes and then the thaw cycle was activated. Heated saline was circulated through the Candela Urethral Warmer for the first 14.5 minutes of the procedure. The rectum and prostate were removed as one unit after the injection of Tripan Blue to stain dead tissue. The only complication was a capsule of kidney ripped during thaw, but minimal bleeding occurred. The freeze profile of the cryoprobes on the side of the probe closest to the Candela Urethral Warmer was smaller.

A similar study also was conducted with a 40 pound slab of beef liver. The slab of liver was allowed to thaw and a flap was created. The Candela Urethral Warmer was placed in the pocket created by the open flap and the flap was closed. Two probe was sutured in place near the edge of the balloon catheter with one probe on each side. Three thermocouples also were placed on each side. The seventh

thermocouple was placed into the surface of the liver very close to the balloon. The saline and the liver were then preheated. The cryoprobes were activated in the freeze cycle for 13 minutes and the freezing sequence was recorded. The tissue immediately surrounding the urethral balloon catheter remained unfrozen.

Thus, the use of infrared lamps as the heating source for a urethral warmer does not raise any new questions of safety or effectiveness.

Third, the Candela Urethral Warmer and the CMS Urethral Warmer use different technologies to ensure that the saline is flowing through the catheter. The Candela Urethral Warmer has a low volume alarm. The CMS Urethral Warmer has a flow indicator that indicates whether the saline is flowing. Bench testing was conducted with open ended tubing to determine how much saline must be lost to activate the Candela Urethral Warmer's low volume alarm. A set of tests was run with 15 minute intervals between the three samples. The data from the second set of tests shows the low volume alarm sounds when an average of 1,110 ml of saline from the bottle, including the 500 ml of priming volume, is lost. Thus, this testing demonstrates that the Candela Urethral Warmer's low volume alarm does not raise any new questions of safety or effectiveness.

Fourth, the Candela Urethral Warmer and the CMS Urethral Warmer have different configurations. The Candela Urethral Warmer is housed in a console. The CMS Urethral Warmer is mounted on an IV pole. However, the purpose of both configurations is to transfer heat to the saline, with no real

difference in the end result, namely, the proper heating of the saline. Thus, the Candela Urethral Warmer's configuration does not raise any new questions of safety or effectiveness.

Fifth, the saline flows through the devices in different directions. The saline flows through the Candela Urethral Warmer in one direction. The saline flows cross current through the CMS Urethral Warmer. However, both devices employ closed loop catheters that recirculate the saline, *i.e.,* the saline flows from the saline container through the delivery tubing, the balloon catheter, and the return tubing back to the saline container. Thus, the Candela Urethral Warmer's unidirectional flow of the saline does not raise any new questions of safety or effectiveness.

Sixth, the Candela Urethral Warmer's delivery tubing and balloon catheter are made of different materials than the CMS Urethral Warmer's delivery tubing and balloon catheter. Bench testing was conducted to determine whether the Candela Urethral Warmer could withstand normal working pressure. The pressure in the system was recorded after the pump was started. The return tubing was blocked at one point. The pressure in the system was then recorded. Destruction of the joint between the balloon catheter and the return tubing was observed but the delivery and return tubings and the balloon catheter did not burst at a pressure that was more than three times the normal operating pressure.

In addition, testing was conducted on the Candela Urethral Warmer with a pressure gauge connected between the balloon catheter and the return tubing to determine whether the balloon catheter continues to inflate as the pump setting is increased, and thus, the saline flow rate is increased. The pump speed was increased from "one" to "five." There was no significant difference in the priming volume and balloon catheter diameter with pump settings of "3" or higher. Based on these test results, it was determined that the Candela Urethral Warmer's balloon catheter is compliant, *i.e.,* the balloon catheter will not inflate beyond a fixed size regardless of the flow rate of the saline or the back pressure.

Furthermore, the materials used to construct the Candela Urethra Warmer's delivery tubing, balloon catheter, sound and radiopaque marker have been demonstrated to be biocompatible by their similar use in products that have received premarket clearance. The biocompatibility of the silicon tubing was demonstrated by biocompatibility data. Thus, the use of these materials does not raise new questions of safety or effectiveness.

In summary, descriptive information and performance data demonstrate that the Candela Urethral Warmer's different technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Candela Urethral Warmer is substantially equivalent to the CMS Urethral Warmer.